K101945

JAN 2 6 2011

510(k) Summary

JJGC Indústria e Comércio de Materiais Dentários SA
Neodent Implant System

January 25, 2011

ADMINISTRATIVE INFORMATION

Manufacturer Name:	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 – CIC Curitiba - PR - CEP, 81270-200, Brazil Telephone: +55 41 2169 4071 Fax: +55 41 2169 4046
Official Contact:	Daniel Lecuona
Representative/Consultant:	Linda K. Schulz, BSDH, RDH Kevin A. Thomas, PhD PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130, USA Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 email: lschulz@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Neodent Implant System
Common Name:	Endosseous dental implant Endosseous dental implant abutment
Classification Regulations:	21 CFR 872.3640
Product Code:	DZE NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

DEVICE DESCRIPTION

The Neodent Implant System implants included in this submission are threaded, self tapping, root form, endosseous dental implants with a Morse taper abutment interface. They are made of commercially pure titanium, with a surface that is grit blasted and acid etched. Implants are provided in both a straight, double thread design and a tapered, single thread design. In addition, multiple abutments are provided for each diameter implant for both cement-retained and screw-retained prostheses.

TESTING

Testing was performed in conformance to ISO 14801 *Dentistry - Implants - Dynamic fatigue tests for endosseous dental implants* to ensure that the strength of the Titamax CM Implants in conjunction with CM Abutments is appropriate for the intended use. Results confirmed the strength of the system.

EQUIVALENCE TO MARKETED DEVICE

The Neodent Implant System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Lifecore Biomedical Stage-1 Single Stage RBM Dental Implant System cleared under K003226,
Lifecore Biomedical Stage-1Angled Abutment System cleared under K032495,
Dentsply International, Inc., ANKYLOS® C/X Dental Implant System cleared under K083805,
Nobel Biocare NOBELSPEEDY™ Implants cleared under K050406,
Nobel Biocare Esthetic Zirconia Abutment cleared uinder K031719,
Straumann ITI® Dental Implant System cleared under K033922,
Straumann synOcta® Prosthetics cleared under K041295,
Straumann UCLA Gold Abutment cleared under K022859, and
Astra Tech Fixture MicroThread™ OsseoSpeed™ cleared under K053384,
JJGC Indústria e Comércio de Materiais Dentários SA Neodent Implant System cleared under K101207.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium conforming to ASTM F67 and have similar surface treatments. The subject and

predicate abutments are also made of the same materials (titanium alloy, gold alloy, zirconia). The subject and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, height, and gingival height of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods.

Overall, Neodent Implant System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JJGC Industria Commercio e Comercio de Materiais Dentarios SA
C/O Linda K. Schulz
Paxmed International, LLC
11234 El Camino Real. Suite 200
San Diego, California 92130

JAN 26 2011

Re: K101945
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: DZE, NHA
Dated: January 13, 2011
Received: January 14, 2011

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101945

Device Name: Neodent Implant System

Indications for Use:

The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of __

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101945